

<b>TO:</b> <b>Mail Stop 8</b> <b>Director of the U.S. Patent and Trademark Office</b> <b>P.O. Box 1450</b> <b>Alexandria, VA 22313-1450</b>	<b>REPORT ON THE</b> <b>FILING OR DETERMINATION OF AN</b> <b>ACTION REGARDING A PATENT OR</b> <b>TRADEMARK</b>
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In compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Maryland on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. JFM-11-1103	DATE FILED 4/27/11	U.S. DISTRICT COURT FOR THE DISTRICT OF MARYLAND 101 W. Lombard St. Baltimore, MD 21202	
PLAINTIFF  Genzyme Corporation		DEFENDANT  Endo Pharmaceuticals Inc.	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK	
1 5,667,775			
2			
3			
4			
5			

In the above-entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK	
1			
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In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT
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CLERK Felicia C. Cannon	(BY) DEPUTY CLERK
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DATE 4/27/11
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Copy 1—Upon initiation of action, mail this copy to Director    Copy 3—Upon termination of action, mail this copy to Director  
 Copy 2—Upon filing document adding patent(s), mail this copy to Director    Copy 4—Case file copy

GENZYME CORPORATION  
500 Kendall Street  
Cambridge, Massachusetts 02142

**V.**

) Civil Action No.:

**ENDO PHARMACEUTICALS INC.**  
100 Endo Boulevard  
Chadds Ford, Pennsylvania 19317

**Resident Agent  
The Corporation Trust Incorporated  
300 E. Lombard Street  
Baltimore Maryland 21202**

**Defendant.**

Plaintiff Genzyme Corporation, by and through its attorneys, and for its Complaint herein against Defendant Endo Pharmaceuticals Inc., hereby alleges as follows:

1. This is an action for patent infringement.

2. Plaintiff Genzyme Corporation (“Genzyme”) is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

3. On information and belief, Endo Pharmaceuticals Inc. ("Endo") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

#### **JURISDICTION AND VENUE**

4. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, Endo engages and has engaged in systematic and continuous contacts with Maryland, and has purposely availed itself of the benefits and protections of the laws of the State of Maryland.

6. This Court has personal jurisdiction over Endo by virtue of, *inter alia*, the above-mentioned facts.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

#### **CLAIM FOR RELIEF**

8. Genzyme holds approved New Drug Application ("NDA") No. 022-127 for Renvela® tablets, 800 mg, which product contains the active ingredient sevelamer carbonate.

9. Renvela® tablets were approved by the Food and Drug Administration (the "FDA") on October 19, 2007, and currently are indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

10. Genzyme owns United States Patent No. 5,667,775 ("775 patent"), titled "Phosphate-Binding Polymers for Oral Administration." The '775 patent was duly and legally issued on September 16, 1997, and was originally assigned to GelTex Pharmaceuticals, Inc.,

which was acquired by Genzyme in 2000. A true copy of the '775 patent is attached hereto as Exhibit A.

### **PATENT INFRINGEMENT BY ENDO**

11. Genzyme repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

12. By a letter dated March 22, 2011 purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) ("Endo's Notice Letter"), Endo informed Genzyme that it had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 202616 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of generic 800 mg sevelamer carbonate tablets ("Endo's Sevelamer Carbonate Tablets") prior to the expiration of the '775 patent.

13. Endo's Notice Letter informed Genzyme that, as part of ANDA No. 202616, Endo had filed a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and opined that the '775 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale and/or importation of Endo's Sevelamer Carbonate Tablets.

14. By submitting ANDA No. 202616 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Endo's Sevelamer Carbonate Tablets prior to the expiration of the '775 patent, Endo has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

15. On information and belief, the offer for sale or sale of Endo's Sevelamer Carbonate Tablets, if approved by the FDA, would induce infringement of, and/or be contributory infringement of the '775 patent under 35 U.S.C. § 271.

16. Genzyme is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 202616 be a date which is not earlier than the expiration of the '775 patent, and any other exclusivity to which Genzyme is or becomes entitled.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff respectfully requests the following relief:

A. A Judgment declaring that Endo's filing of ANDA No. 202616 is an act of infringement under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment declaring that the offer for sale or sale of Endo's Sevelamer Carbonate Tablets, if approved by the FDA, would induce infringement of, and/or be contributory infringement of the '775 patent under 35 U.S.C. § 271;

C. An Order that the effective date of any FDA approval of Endo's ANDA No. 202616 be no earlier than the date on which the '775 patent expires, and any other exclusivity to which Genzyme is or becomes entitled;

D. Preliminary and permanent injunctions enjoining Endo, its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Endo's Sevelamer Carbonate Tablets until after the expiration of the '775 patent, and any other exclusivity to which Genzyme is or becomes entitled;

E. The costs and reasonable attorney fees of Genzyme in this action; and

F. Such further and other relief as this Court may deem just and proper.

/s/ George E. Brown  
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